

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:

Toshihiro ITO et al.

Application No.: 10/542,200

Confirmation No.: 3457

Filed: July 15, 2005

Art Unit: 1794

For: ENRICHED RICE OR ENRICHED WHEAT

Examiner: P. GEORGE

DECLARATION 37 C.F.R. § 1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Noboru Sakaguchi, do declare and say as follows:

1. I am a co-inventor of above-identified application.
2. I am thoroughly familiar with the contents of the above-identified application, including the Final Office Action dated October 29, 2010 and understand its contents.
3. I have read and understand the contents of the references cited in the October 29, 2010 Office Action, including the references of Misaki '996 (U.S. Patent No. 4,765,996), Kwak '997 (U.S. Patent No. 6,402,997), Nanbu '675 (U.S. Patent No. 6,074,675), Tamaki '462 (U.S. Patent No. 6,436,462) and WO '065 (WO 2008/140065).
4. In the October 29, 2010 Office Action at page 2, the Examiner states that the experimental data in the previously submitted Declaration under 37 C.F.R. § 1.132 filed on September 27, 2010 is not commensurate in the scope of the claims. The Examiner also states

that there is a lack of showing of statistical results that provide evidence, versus singular data points which do not rule out uncertainty. I provide the following explanation directed to the Examiner's comments.

5. The present invention is directed to:
- iron-enriched and vitamin-enriched rice or barley;
  - wherein the rice grains or barley grains are coated with an emulsifying agent-coated iron salt composition or coated with a polyglycerol fatty acid ester;
  - the iron salt has an average particle diameter range of 0.05 to 0.8  $\mu\text{m}$  or 0.05 to 0.5  $\mu\text{m}$ ; and
  - the emulsifying agent is an enzymatically decomposed lecithin.

An analysis of Enriched Rice Nos. 1-4 of the Rule 132 Declarations show that any difference in terms of residual ratio (%) and loss percentage (%) is due to just one factor - - the enzymatically decomposed lecithin. The other ingredients (e.g., whether rice or barley is tested; etc.) do not affect the experimental results as explained below. In summary, based on the knowledge in the art, and the results from my previously filed Declarations along with the experimental data in the specification of this application, the experimental data to date is sufficient to show unexpected, superior results for the scope of the claims, and there is enough data to eliminate any scientific uncertainty.

#### Rice and barley

Both of rice and barley are grains wherein there is no substantial difference in the surface state and form between the two. Accordingly, either rice or barley would give experimental results for the presently claimed invention (i.e., in terms of residual ratio (%) loss percentage (%) of iron and vitamins) that are the same or similar as those shown in the Rule 132 Declarations.

#### Hydrogenated oils

Hydrogenated oils, also discussed in the specification at page 9, are used for avoiding

removal of iron salts coated on rice upon washing. As far as being solid at a normal temperature, any type of hydrogenated oil would give results are the same or similar as those shown in the Rule 132 Declarations.

#### Enzymatically decomposed lecithin

As far as being enzymatically decomposed, the hydrophilicity of lecithins is improved by enzymatic treatment. Any type of enzymatically decomposed lecithins would give results that are the same or similar as those shown in the Rule 132 Declarations.

#### Polyglycerol fatty acid esters

The polyglycerol fatty acid esters, also discussed in the specification at pages 9-10, are used for modifying properties of hydrogenated oils. In particular, the particle size of the hydrogenated oil can be adjusted with use of the polyglycerol fatty acid ester. Any type of polyglycerol fatty acid ester can be employed and would give results that are the same or similar as those shown in the Rule 132 Declarations.

#### Particle diameter range

It is preferred that the particle size be relatively small and small as possible. At the beginning stages of production, iron salts are fine particles but the particle size becomes larger due to secondary and tertiary aggregations during production. It is thus technically difficult to prepare fine particles of iron salts having particle sizes that are lower than 0.05  $\mu\text{m}$ .

The Examples of the present application have iron salts with the particle diameter of 0.8  $\mu\text{m}$ . Still, there is no problem in producing particles between the range of 0.05 – 0.8  $\mu\text{m}$ . Testing iron salts such that the particle size is anywhere from 0.05 to 0.8  $\mu\text{m}$  would give results that are the same or similar as those shown in the Rule 132 Declarations.

#### Conclusion

Thus, based on the results from my previously filed Declarations along with the experimental data in the specification of this application, the experimental data is sufficient to

show unexpected, superior results for the scope of the claims and there is enough data to eliminate any scientific uncertainty.

6. I hereby declare that all statements made herein of my own knowledge are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: January 26, 2011

By: N. Sakaguchi  
Noboru SAKAGUCHI